Supreme Court, U.S.
FILED
FEB 25 1988
JOSEPH F. SPANIOL, JR.
CLERK

No. 87-498

IN THE
Supreme Court of the United States
OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

---

JOINT APPENDIX

ELLEN M. VIAKLEY *
BERGER KAPETAN MALAKOFF
& MEYERS, P.C.
5th Floor, Law & Finance Building
429 Fifth Avenue
Pittsburgh, PA 15219
(412) 281-4200
Counsel for Petitioners

* Counsel of Record

CHARLES FRIED *
Solicitor General
RICHARD K. WILLARD
Assistant Attorney General
JOHN F. CORDES
WILLIAM COLE
Attorneys
Department of Justice
Washington, D.C. 20530
(202) 633-2217
Counsel for Respondents

PETITION FOR CERTIORARI FILED SEPTEMBER 25, 1987
CERTIORARI GRANTED JANUARY 11, 1988

JOINT APPENDIX
INDEX

Docket Entries	Page
District Court	1
Court of Appeals	6
Complaint	8
Motion to Dismiss	18
Judgment of Court of Appeals	20

NOTICE

The following opinions and orders have been omitted in printing this Joint Appendix because they appear on the following pages in the printed Appendix to the Petition for a Writ of Certiorari, which is incorporated herein by reference.

	Page
Order and Opinion of Court of Appeals, June 30, 1986	Pet. App. 1a
Order and Opinion of District Court, April 30, 1986	Pet. App. 28a

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs

v.

UNITED STATES OF AMERICA,

Defendants

RELEVANT DOCKET ENTRIES

DATE	NR.	PROCEEDINGS
1984		
Dec 5	1	Complaint Filed.
Dec 5	—	Summons Issued
1985		
Feb 11	2	Motion for Enlargement of time to File answer filed by the Deft with a Proposed order.
Feb 19	W/2	Order of Court entered Feb 19 1985 directing that deft U.S.A. shall have until Feb 26 1985 within which to file an Answer (Mansmann J)
Feb 25	3	Deft United States of Americas Motion to Dismiss filed with a proposed order.
Feb 28	4	Order of Court entered Feb 27 1985 directing that the Deft U.S.A. having filed a motion to Dismiss together with a memorandum in sup-

DATE	NR.	PROCEEDINGS
1985		
		port, IT is Ordered that Pltfs file a response to the Above motion together with memorandum in support on or before Mar 11 1985 (Mansmann J)
May 6	—	The above case is Re Assigned to Judge Diamond.
Jun 26	5	Order of Court fixing Pre Trial Procedure entered Jun 25 1985 directing that all discovery be Completed by Oct 23 1985 (Diamond J)
Jul 12	6	Motion to Stay Discovery and Vacate June 25 1985 order of the Court fixing pre trial procedure filed by the deft U.S.A.
Sept 10	7	Memorandum Order entered Sept 10 1985 directing that deft having filed a motion to stay discovery and vacate the Jun 25 1985 order of this court fixing pre trial procedure and brief, It is ordered that since there appears to be a legal question raised by the motion that may result in an entire dismissal of the action the court will make an exception to its standard pre trial order and Grant the motion to Stay (Diamond J)
Oct 30	8	Order of Court entered Oct 30 1985 directing that the Pltfs in the above case indicate to the Court within 10 days from the date of this order whether pltfs intend to prove that the alleged negligent conduct of the Deft either increased the risk of harm to the Pltf Kevin Berkovitz or that the alleged harm suffered by Pltf Kevin Berkovitz was due to reliance upon the Defts Conduct (Diamond J)
Nov 1	9	Response to Order of Court of Oct 30 1985 filed.

DATE	NR.	PROCEEDINGS
1986		
Feb. 12	10	Supplement to Defendant J. A's motion to dismiss or in the alternative for summary judgment filed
Mar 3	11	Pltfs Answer to the Supplement to Defts United States of America Motion to Dismiss or in the alternative for Summary Judgment filed.
Apr 30	12	Memorandum Opinion Filed (Diamond J)
Apr 30	13	Order of Court entered Apr 30 1986 directing thta the Pltfs are Granted Leave to Amend their Complaint and It is further ordered that Defts Motion to Dismiss is Denied (Diamond J)
May 8	14	Order of Court entered May 7 1986 fixing pre trial procedure and all Discovery be Completed by July 7 1986
May 9	15	ANSWER Filed by the Deft U.S.A.
Jun 5	16	United States Motion for Reconsideration or in the Alternative for Certification for interlocutory Appeal filed with a Proposed order.
Jun 16	17	Pltf's motion to extend time for discovery and compliance with pretrial deadlines in view of deft's failure to respond to existing discovery and in view of deft's motion for reconsideration or, in alternative, certification filed.
June 16	18	Pltf's opposition to motion of U.S. for reconsideration and statement of no opposition to motion of U.S. for certification for interlocutory appeal filed.
June 16	19	Amended complaint filed by pltf. amending body of pltf

DATE	NR.	PROCEEDINGS
1986		
June 19	W-16	Order dated 6/18/86 entered on motion filed 6/5/86 grating deft's motion for reconsideration or alternatively, for certification for interlocutory appeal and that upon reconsideration this court reaffirms its memor. opinion dated 4/30/86 and hereby incorporates its ruling herein by reference and that this order including the memo. ruling incorporated by reference herein, involves a controlling question of law to which there is substantial ground for difference of opinion and that immediate appeal may materially advance the ultimate determination of this litigation and it is ordered that its incorporated Memo. order of 4/30/86 is hereby certified to U.S. Court of Appeals pursuant to 28 U.S.C. 1292(b) and further ordered that defts motion for reconsideration or alternatively, for certification for interlocutory appeal is granted with respect to certification for interlocutory appeal (Diamond, J.)
Jul 9	20	Stipulation to stay discovery during the pendency appeal filed with a proposed order.
Jul 14	W/20	Order of Court entered Jul 14 1986 directing that Discovery shall be Stayed pending acceptance by the U.S. Court of Appeals of the Interlocutory Appeal of the instant Action and If the Third Circuit accepts the Interlocutory appeal of the above action Discovery shall be stayed pending the resolution of the appeal and if the Third Circuit declines to accept the Interlocutory appeal of the above action, the parties agree to confer regarding the Establishment of a discovery schedule (Diamond J)

DATE	NR.	PROCEEDINGS
1986		
Jul 21	21	Certified copy of Order dated Jul 17 1986 received from the U.S. Court of Appeals directing that Petition for Permission to take and Interlocutory Appeal, in which it states that Pltfs did not oppose the Motion for Certification of an Interlocutory appeal in the District Court, and the Foregoing Motion is Granted (Adams J)
Jul 21	—	Letter and Copy of June 18 1986 order mailed to the U.S. Court of Appeals with Certified copy of the Docket Sheet. No filing fee on the Interlocutory Appeal, Filed by the U.S.A. (No Court Reporter) Notice to Counsel of Record.
July 23		TPO mailed Atty Rupert Mitsch, Dept. of Justice, appellant
Jul 28	22	Transcript Purchase order filed by the U.S.A. and Indicating that a transcript is Unnecessary for appeal purposes.
Jul 28	—	The above case is Complete for Appeal Purposes, and Three Copies of the Docket Sheet mailed to the U.S. Court of Appeals, One Certified
Jul 30	—	Notice received from the U.S. Court of Appeals advising that the above case was Docketed at (86-3444)
Aug 1	—	Receip received from the U.S. Court of Appeals of the Certified List in Lieu of the Record.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Docket No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

v.

UNITED STATES OF AMERICA,
Appellant

RELEVANT DOCKET ENTRIES

DATE	FILINGS--PROCEEDINGS
1986	
July 17	NOA FILED
July 28	DOCKETED:
1987	
Jan. 14	Ltr. dtd 1-9-87, from Ellen R. Viakley, Esq., cnsel for aplees, sent for Ct's info, filed. (ms)
Feb. 19	Ltr dtd 2-18-87, from aplts' cnsel, rec'd for Ct.'s info. (ms)
Feb. 19	At oral argmt. cnsl was directed to arrange for transcript of oral argmt. for the Ct. (ab)
Feb. 19	ARGUED/SUBMITTED
March 4	Transcript of oral argument rec'd for info of ct (as)
May 26	Let dtd 5-22-87 from aplee with enc. pursuant to Rule 28(j) F.R.A.P., rec'd for Ct's info. (ms)

DATE	FILINGS—PROCEEDINGS
1987	
June 19	Letter dated 6/18/87, from Nanette R. Everson, esq., counsel for appellant, pursuant to Rule 28(j), F.R.A.P. (mgp)
June 30	OPINION
	JUDGMENT reversing & remanding to DC with dir. to grant government's summary judgment mot. csts txd agnst appellee (sa)
July 14	PET. FOR REHG. by appellee w/serv. (sa)
July 22	Denied. Judges Higginbotham, Becker & Mansmann would grant rehg.
July 28	Mot. by appellee to stay the mandate to & including Aug. 28, 1987, w/serv. filed (sa)
July 30	Order (Sloviter, Cir. Judge) granting the above mot. filed (sa)
Aug 13	Mot. by appee. for further stay of mandate to & incldg. 9/28/87 w/serv. fid. (sa)
Aug 14	Order (Sloviter) granting above mot. fld. (sa)

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents and natural guardians, ARTHUR BERKOVITZ and DONNA BERKOVITZ, his wife; and ARTHUR BERKOVITZ and DONNA BERKOVITZ in their own rights,

Plaintiffs

vs.

UNITED STATES OF AMERICA,

Defendant.

COMPLAINT

First Count

Kevan Berkovitz, a minor, Plaintiff vs. United States of America, Defendant.

1. Minor Plaintiff, Kevan Berkovitz is resident of Belle Vernon, Washington County, Pennsylvania, where he resides with his parents, Arthur Berkovitz and Donna Berkovitz, the other Plaintiffs herein.

2. Defendant, United States of America, is a sovereign and is subject to suit under the Federal Tort Claims Act, 28 U.S.C. Section 1346 *et seq.*, and 28 U.S.C. Section 2680 *et seq.*

3. On or about May 10, 1979, minor Plaintiff was administered Orimune, the Sabin Oral Poliomyelitis Vaccine (hereinafter "SOPV"), manufactured by Lederle Laboratories, a division of the American Cyanamid Company (hereinafter "Lederle Laboratories"). Said vaccine was administered to minor Plaintiff by his pediatrician in North Charleroi, Pennsylvania.

4. On or about June 4, 1979, as a result of the administration of the said vaccine, minor Plaintiff sustained paralytic poliomyelitis and other injuries more fully described hereafter.

5. Defendant, through its agency, the Communicable Disease Center, Atlanta, Georgia, and its agents, servants and employees, determined that minor Plaintiff's paralytic poliomyelitis was a result of the SOPV administered to minor Plaintiff, and further, that minor Plaintiff had suffered a Type 3 vaccine-associated case of poliomyelitis.

6. Prior to minor Plaintiff being administered Orimune, Defendant, pursuant to its duty, had promulgated rules and regulations for the manufacture, sale and licensure of SOPV. Said rules and regulations were published in the Federal Register and had the force of law.

7. Under the rules and regulations promulgated, Defendant had the further duty to assure that the SOPV would meet the requirements of the regulations in order to assure the safety, purity and potency of the said product to recipients such as minor Plaintiff and to persons coming in contact with recipients.

8. These initial regulations were contained in the code of federal regulations at 42 C.F.R., 73.110 *et seq.* These regulations were promulgated March 25, 1961, to become effective April 24, 1961.

9. On March 16, 1968, parts of the aforementioned regulations were modified and published in the Federal Register, Volume 33, No. 53. Thereafter, the rules and regulations were again modified and are contained in 21 C.F.R., 630.10 *et seq.*

10. Defendant was and is charged with the responsibility of assuring compliance with the said regulations

by manufacturers of SOPV, including, but not limited to, Lederle Laboratories.

11. As a result of the negligence of Defendant, by and through its agents, servants and employees, minor Plaintiff sustained paralytic poliomyelitis following the administration of Orimune in the office of minor Plaintiff's pediatrician on May 10, 1979.

12. The initial symptoms of the vaccine-associated illness suffered by minor Plaintiff as a result of the negligence of Defendant were first manifested on June 4, 1979.

13. On May 8, 1981, notice of claim was sent to Defendants' Department of Health and Human Services, Washington, D.C. 20201, in accordance with the Federal Tort Claims Act, 28 U.S.C. Section 1346, *et seq.*, 28 U.S.C. Section 2680.

14. More than six months has passed since the date of said notice of claim and no formal rejection of the notice has been made by the Department of Health and Human Services or any other authorized governmental agency.

15. The duty to administer, regulate and supervise the manufacture, licensure, sale and distribution of SOPV and the enforcement of the regulations promulgated for the above purpose was initially the responsibility of Defendants' National Institutes of Health, Division of Biologic Standards. This responsibility was thereafter transferred to Defendants' Food and Drug Administration, Bureau of Biologics. All of these agencies are or were agencies of Defendant's Department of Health and Human Services, previously known as The Department of Health, Education and Welfare.

16. At the time of the original licensure of SOPV, the division responsible for the granting of such licensure was Defendant's Division of Biologic Standards.

17. The Division of Biologic Standards was negligent in some or all of the following particulars:

(a) In failing to assure that Lederle Laboratories, the manufacturer of Orimune complied with applicable regulations, including, but not limited to: 42 C.F.R. 73.110(b)(2); 42 C.F.R. 73.110(b)(4); 42 C.F.R. 73.110(b)(5); 42 C.F.R. 73.114(b)(1); 42 C.F.R. 73.114(b)(1)(i)(ii)(iii); 42 C.F.R. 73.114(b)(3); 42 C.F.R. 73.117; 42 C.F.R. 73.116(a); 42 C.F.R. 73.116(c);

(b) In improperly relying upon studies performed by the Union of Soviet Socialist Republics to form the basis of the testing for the licensing of said vaccine under 42 C.F.R. 73.110, inasmuch as: The vaccine administered to the Russian population was a vaccine different than that licensed and produced by the United States of America; the vaccine administered to the Russian population was administered in a different dosage than that required under 42 C.F.R. 73.110, *et seq.*; the population receiving said vaccine was not demonstrated to be susceptible to poliomyelitis by blood tests, stool examinations or other appropriate methods; the Russian studies did not include the number of susceptible persons required by the regulations; and the epidemiologic surveillance of neurological illness was not adequate according to standards required by 42 C.F.R. 73.110 *et seq.*;

(c) In failing to prevent the said SOPV from being licensed in the United States, when Defendant, through its Communicable Disease Center, through its Division of Biologic Standards and through its Surgeon General's Office, knew that prior to the approval of the licensure for Lederle Laboratories cases of paralytic poliomyelitis were occurring with SOPV administered in Russia in such a number as to fail

the requirements necessary for licensure under 42 C.F.R. 73.110(b)(2);

(d) In licensing Lederle Laboratories for the manufacture of SOPV in the absence of the manufacturer's demonstrated compliance with the applicable regulation 42 C.F.R. 73.110(b)(4), which required that the seed virus utilized for the manufacture of SOPV was to be tested intrathalamically, intraspinally and intramuscularly, in conjunction with a comparative analysis with the applicable reference strain;

(e) In permitting the distribution of trivalent vaccine administered to minor Plaintiff when the seeds, from which the monovalent pools utilized in said trivalent vaccine were manufactured, had not been tested in accordance with the requirements of 42 C.F.R. 73.110(b)(4);

(f) In licensing Lederle Laboratories for the manufacture of SOPV in contravention of the applicable regulation, 42 C.F.R. 73.110(b)(2), requiring the manufacturer to furnish studies indicating that 100,000 people, demonstrated to be susceptible by blood tests, stool examinations and other appropriate methods with regard to Type 1, Type 2 and Type 3 SOPV and/or trivalent SOPV, had been administered said vaccine under circumstances where adequate epidemiological surveillance of neurological illness had been maintained;

(g) In licensing Lederle Laboratories for the manufacture of SOPV when the five original licensing monovalent pools and trivalent lots, submitted to qualify SOPV for licensure, had failed neurovirulence tests as to certain Type 1 and Type 3 monovalent virus pools;

(h) In failing to enforce regulation 42 C.F.R. 73.110(b)(5) which required requalification of the

seed virus in accordance with 42 C.F.R. 73.110(b)(4), when there was a change in the neurovirulence of the production virus used by the manufacturer;

(i) In generally failing to require Lederle Laboratories to test the seeds for each type of SOPV in accordance with applicable regulations or to require Lederle Laboratories to submit evidence of such tests;

(j) In otherwise being negligent under the circumstances.

18. In or about 1972 and thereafter, enforcement of the regulations governing the licensing, manufacture and distribution of SOPV became the designated responsibility of the Bureau of Biologics, Food and Drug Administration.

19. The Bureau of Biologics was negligent in some or all of the following particulars:

(a) In violating the rules and regulations governing the licensure, manufacture and distribution of SOPV at 42 C.F.R. 73.110 *et seq.* and 21 C.F.R. 630.10 *et. seq.*;

(b) In undertaking responsibility to test for safety various lots of SOPV Type 1, Type 2 and Type 3, and then in releasing said lots even though testing by Defendant disclosed that the lots failed to meet the necessary requirements for safety, purity and potency, which lots were distributed to individuals, including, but not limited to, minor Plaintiff herein;

(c) In failing to monitor, correct, supervise, regulate or otherwise determine the basis of the inconsistency of the manufacturer's testing and results of said testing in comparison with Defendants test results performed simultaneously on the same vaccine lots, all of which resulted in minor Plaintiff sustaining paralytic poliomyelitis as a result of said negligence;

(d) In otherwise being negligent as described in paragraph 17 above, as though said allegations were repeated herein in their entirety;

(e) In otherwise being negligent under the circumstances.

20. Defendant, by its agents, servants and employees, including, but not limited to the Food and Drug Administration and the Bureau of Biologics, was negligent in some or all of the following particulars:

(a) In failing to withdraw from the market the SOPV, specifically, the said vaccine manufactured by Lederle Laboratories, when Defendant knew, or should have shown, that the said vaccine failed to meet each and every one of the requirements and regulations necessary to insure the safety, purity and potency of the said vaccine;

(b) In failing to adequately enforce compliance on the part of Lederle Laboratories with the regulations pertaining to the giving of adequate warnings and precautions for the administration of the SOPV as were necessary;

(c) In failing to require Lederle Laboratories to provide adequate and accurate warnings, both as to statistical risk of disease, and also, as to the fact of non-compliance of various lots of vaccine with the regulations enacted to assure the safety, purity and potency of said vaccine;

(d) In otherwise being neligent under the circumstances.

21. As a result of the negligence of Defendant and its agents, servants and employees, minor Plaintiff suffered the severe and permanent paralysis of bulbar poliomeylitis, affecting, among other parts of his body, his four extremities and the muscles and other structures of his chest. He suffered severe respiratory distress, atelectasis of the lungs and associated hypoxemia. He suffered a severe scoliosis of the spine with the curvature being as great as 90 degrees. He suffered severe emotional and nervous shock and distress. All of the foregoing injuries are permanent in nature.

22. As a result of the bulbar poliomyetlitis, minor Plaintiff was confined to the Mercy Hospital of Pittsburgh from the time he was 2½ months of age on June 4, 1979 until April 18, 1980, when he was over a year old. Because of his paralysis which prevented him from breathing, a tracheostomy was performed, placing a permanent hole in his trachea, through which minor Plaintiff was maintained on a respirator. Minor Plaintiff continues to require ventilatory assistance periodically during the day as of the date of this Complaint. Following his discharge from Mercy Hospital, minor Plaintiff was additionally confined for rehabilitative care at the Rehabilitation Institute of Pittsburgh and, since that time, has been cared for on a full-time basis with 24 hour monitoring by his mother, father and sister. Minor Plaintiff has been forced to undergo surgery on various occasions in an attempt to reduce the scoliosis of his spine by the insertion of Harrington rods. Minor Plaintiff has been deprived of the use of his legs, his arms and his hands and must either be carried or conveyed from place to place with the use of a wheel chair; minor Plaintiff will be confined to same for the rest of his life. Minor Plaintiff has required respiratory care and management on a daily basis and will require same for the rest of his life. Minor Plaintiff has suffered from atrophy and contracture of all four of his limbs, as well as the musculature of other portions of his body, and will suffer same for the rest of his life.

23. As a further result of his injuries, in addition to the medical, surgical, medicinal, and rehabilitative care which minor Plaintiff has endured in the past, and in addition to the hospitalizations in the past, minor Plaintiff will be forced to submit to additional care and hospitalizations for the rest of his life.

24. As a further result of his injuries, minor Plaintiff has been forced to endure great pain, suffering, emotional distress and inconvenience and will endure same for the rest of his life. He suffers permanent disfigurement. He suffers from the embarrassment and humiliation resulting from same and will be forced to endure additional embarrassment and humiliation for the rest of his life.

25. As a further result of minor Plaintiff's injuries, he has been forced to be confined to his home at those times when he has not been confined in hospitals and other specialized rehabilitative facilities, and he will be forced to be confined to said home or facilities for the rest of his life.

26. As a further result of his injuries, minor Plaintiff's education and schooling and his opportunity to form normal and enriching social relationships has been retarded and will be retarded in the future. Both his earning capacity and his ability to participate in and enjoy the normal pleasures of life have been severely and permanently impaired.

27. As a further result of minor Plaintiff's injuries, he will be forced to expend large sums of money for doctors, hospitals and other items necessary for his care and treatment after he attains his majority.

Second Count

Arthur Berkovitz and Donna Berkovitz, his wife, in their own rights, Plaintiffs vs. United States of America, Defendant.

28. Plaintiffs incorporate by reference and make a part of this Count, all of the paragraphs of the First Count of this Complaint.

29. As a result of the injuries suffered by their son, the minor Plaintiff herein, Plaintiffs have been forced to expend large sums of money for hospitals, doctors, nurses and other items necessary for the proper care and treatment of their son, and they will be forced to expend

additional sums for like items in the future. To date, the medical care and treatment of minor Plaintiff has resulted in expenses of approximately $350,000.00.

30. As a further result of minor Plaintiff's injuries, Plaintiffs have suffered the loss of the services and companionship of their son and they will suffer similar loss in the future.

31. As a further result of minor Plaintiff's injuries, Plaintiffs have been forced to expend large portions of their time in the care and treatment of minor Plaintiff, and will be forced to do so in the future.

32. As a further result of the conduct of Defendant, Plaintiffs have suffered, and will suffer in the future, severe emotional loss and emotional distress and, in addition, have suffered, and will suffer in the future, the loss of the pleasures, joys and benefits of parenting a child who is able to enjoy the normal activities in which a healthy child participates.

33. As a further result of minor Plaintiff's injuries, Plaintiffs have been forced to expend, and will continue to expend, large portions of their time, physical, mental and emotional energy in the care and treatment of minor Plaintiff and they will be forced ot do so, and to continue to do so, in the future.

WHEREFORE, Plaintiffs claim damages against Defendant in sums in excess of $10,000.00.

BERGER KAPETAN MALAKOFF
& MYERS, P.C.

By: /s/ Daniel M. Berger
DANIEL M. BERGER, Esquire
Attorneys for Plaintiffs

ADLER AND KOPS

By: /s/ Stanley P. Kops
STANLEY P. KOPS
Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT
OF PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents, and natural guardians, ARTHUR BERKOVITZ and DONNA BERKOVITZ, his wife; and ARTHUR BERKOVITZ and DONNA BERKOVITZ in their own rights,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

DEFENDANT UNITED STATES OF AMERICA'S MOTION TO DISMISS

Defendant, United States of America, hereby moves this Court to dismiss the United States from the above-captioned action based on Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure on the grounds that the Court lacks jurisdiction over the subject matter of the act and the complaint fails to state a claim upon which relief can be granted. In support of this motion, the Court is respectfully referred to the attached Memorandum of Points and Authorities.

A proposed form of Order is attached for the Court's convenience.

Respectfully submitted,

RICHARD K. WILLARD
Acting Assistant Attorney General

J. ALAN JOHNSON
United States Attorney

AMY REYNOLDS HAY
Assistant U.S. Attorney

/s/ Jeffrey Axelrad
JEFFREY AXELRAD
Director, Torts Branch

/s/ Brenda Moss Green
BRENDA MOSS GREEN
Trial Attorney, Torts Branch
Civil Division
U.S. Department of Justice
Post Office Box 888
Benjamin Franklin Station
Washington, D.C. 20044
Telephone: (202) 724-7462

Attorneys for the Defendant,
United States of America

Of Counsel:

THOMAS SCARLETT
Chief Counsel

ANN H. WION
Associate Chief Counsel
for Enforcement

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

vs.

UNITED STATES OF AMERICA,
Appellant

(D.C. Civ. No. 84-2893)

On Appeal from the United States District Court
for the
Western District of Pennsylvania—Pittsburgh

Present: HIGGINBOTHAM and SLOVITER, *Circuit Judges* and ROTH, *District Judge**

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Western District of Pennsylvania—Pittsburgh and was argued by counsel February 19, 1987.

---

* Honorable Jane R. Roth, United States District Court for the District of Delaware, sitting by designation.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court entered April 30, 1986, as certified to this Court pursuant to 28 U.S.C. § 1292(b) by order entered June 19, 1986, be, and the same is hereby reversed and the cause remanded to the said District Court with direction to grant the government's summary judgment motion. Costs taxed against the appellee.

ATTEST:

/s/ Sally Mrvos
Clerk

June 30, 1987